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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/582,698	06/13/2006	Eli Ryssdal Andersen	PN03101	6568

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GE HEALTHCARE, INC.  
IP DEPARTMENT  
101 CARNEGIE CENTER  
PRINCETON, NJ 08540-6231

EXAMINER
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PERREIRA, MELISSA JEAN

ART UNIT	PAPER NUMBER
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1618

MAIL DATE	DELIVERY MODE
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06/13/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/582,698	<b>Applicant(s)</b> ANDERSEN ET AL.	
	<b>Examiner</b> Melissa Perreira	<b>Art Unit</b> 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 13 June 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>6/13/06</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Claim Objections***

1. Claim 11 is objected to because of the following informalities: it is a duplicate of claim 9. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1,6,9-11,13-15 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Gibby (US 4,822,594).
4. Gibby (US 4,822,594) teaches of the process for the production of DTPA-bis(anhydride) by reacting DTPA with a molar amount of acetic acid four times that of DTPA and a molar amount of pyridine that is six times the amount of DTPA from 45°C to about 85°C (column 3, lines 52-61), preferably about 65°C for 20h (column 4, example 1).
5. It is respectfully pointed out that instant claim 17 is a product-by-process limitation. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is

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unpatentable even though the prior product was made by a different process. In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed Cir. 1985). See MPEP 2113.

6. Claims 1,6,10,11,13,14 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by deLearie et al. (US 5,508,388).

7. deLearie et al. (US 5,508,388) teaches of the process for the production of DTPA-bis(anhydride) by reacting DTPA with acetic acid and pyridine in the molar ratio of 1.0:3.0:4.5 respectively at various temperatures between 55°C to 74°C for 18-22h (column 5, example 1; column 6, example 2).

8. It is respectfully pointed out that instant claim 17 is a product-by-process limitation. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed Cir. 1985). See MPEP 2113.

### ***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dazzi (US 3,660,388).

11. Dazzi (US 3,660,388) discloses the process for the production of DTPA-bis(anhydride) by reacting DTPA with acetic acid and pyridine at 60°C for 48h (column 6, example 9). The reaction of the tetracarboxylic acids of the disclosure is advantageously performed between room temperature and below the decomposition point of the tetracarboxylic acids (i.e. 10°C up to about 150°C), in excess of the monocarboxylic acid anhydride (i.e. acetic anhydride) and the presence of a tertiary nitrogen base (i.e. pyridine) (column 1, lines 45-55; column 2, lines 68+; column 3, lines 1-8). At the time of the invention it would have been obvious to one ordinarily skilled in the art to utilize acetic anhydride and pyridine for the process for the production of DTPA-bis(anhydride). Dazzi discloses that pyridine is a particularly active base that accelerates the reaction and improves the yields. Furthermore, it is obvious to vary and/or optimize the amount of (compound) provided in the composition, according to the guidance provided by (reference), to provide a composition having the desired properties such as the desired (ratios, concentrations, percentages, etc.). It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

12. It is respectfully pointed out that instant claim 17 is a product-by-process limitation. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability

of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed Cir. 1985). See MPEP 2113.

13. Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wagner et al. (US 4,698,263).

14. Wagner et al. (US 4,698,263) discloses the process for the production of DTPA-bis(anhydride) by reacting DTPA with acetic acid and pyridine for 18h at reflux (column 7, lines 5-7; column 12, lines 1-4). At the time of the invention it would have been obvious to one ordinarily skilled in the art to utilize acetic anhydride and pyridine for the process for the production of DTPA-bis(anhydride) as it is well known in the art. Furthermore, it is obvious to vary and/or optimize the amount of (compound) provided in the composition, according to the guidance provided by (reference), to provide a composition having the desired properties such as the desired (ratios, concentrations, percentages, etc.). It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

15. It is respectfully pointed out that instant claim 17 is a product-by-process limitation. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability

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of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed Cir. 1985). See MPEP 2113.

16. Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gibby (US 4,822,594).

17. Gibby (US 4,822,594) teaches of the process for the production of DTPA-bis(anhydride) by reacting DTPA with a molar amount of acetic acid four times that of DTPA and a molar amount of pyridine that is six times the amount of DTPA at 65°C for 20h (column 4, example 1). The reaction mixture can also be heated from 45°C to about 85°C (column 3, lines 52-61). At the time of the invention it would have been obvious to one ordinarily skilled in the art to utilize acetic anhydride and pyridine for the process for the production of DTPA-bis(anhydride) as it is well known in the art. Furthermore, it is obvious to vary and/or optimize the amount of (compound) provided in the composition, according to the guidance provided by (reference), to provide a composition having the desired properties such as the desired (ratios, concentrations, percentages, etc.). It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

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18. It is respectfully pointed out that instant claim 17 is a product-by-process limitation. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed Cir. 1985). See MPEP 2113.

19. Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over deLearie et al. (US 5,508,388).

20. deLearie et al. (US 5,508,388) teaches of the process for the production of DTPA-bis(anhydride) by reacting DTPA with acetic acid and pyridine in the molar ratio of 1.0:3.0:4.5 respectively at various temperatures between 55°C to 74°C for 18-22h (column 5, example 1; column 6, example 2). At the time of the invention it would have been obvious to one ordinarily skilled in the art to utilize acetic anhydride and pyridine for the process for the production of DTPA-bis(anhydride). deLearie et al. discloses that pyridine is a particularly active base that accelerates the reaction and improves the yields (column 2, lines 59-60). Furthermore, it is obvious to vary and/or optimize the amount of (compound) provided in the composition, according to the guidance provided by (reference), to provide a composition having the desired properties such as the desired (ratios, concentrations, percentages, etc.). It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the

optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

21. It is respectfully pointed out that instant claim 17 is a product-by-process limitation. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed Cir. 1985). See MPEP 2113.

### ***Conclusion***


No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa Perreira whose telephone number is 571-272-1354. The examiner can normally be reached on 9am-5pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MP  
May 29, 2007



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